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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,248	03/27/2001	David Bar-Or	ISC.007/PCT-US	4924

25871 7590 10/02/2002

SWANSON & BRATSCHE L.L.C.  
1745 SHEA CENTER DRIVE  
SUITE 330  
HIGHLANDS RANCH, CO 80129

EXAMINER

SHAHNAN SHAH, KHATOL S

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 10/02/2002

11

Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

**Office Action Summary**

Applicati n No.

09/806,247

Applicant(s)

BAR-OR ET AL.

Examiner

Khatol S Shahnian-Shah

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 July 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-13, 19-22 and 28-82 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-13, 19-22 and 28-82 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

### **DETAILED ACTION**

1. Applicants' amendment received 7-16-2001, paper # 6 is acknowledged. Claims 14-18 and 23-27 were canceled, new claims 65-82 were added and claims 36, 41-42, 47, 52-56, 62-64 were amended.
2. Claims 1-13, 19-22 and 28-82 are pending in the applications.

#### ***Restrictions***

3. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-8 and 79, are drawn to a method for detecting an ischemic event by determining the amount of metal ion bound to albumin.

Group II, claim(s) 9-13 and 80, are drawn to a method for detecting an ischemic event by determining the amount of un bound metal ion.

Group III, claim(s) 19-22 and 81, are drawn to a method for detecting an ischemic event by determining the amount of endogenous copper.

Group IV, claim(s) 28-32, are drawn to a method for detecting an ischemic event by determining the amount of albumin derivatives.

Group V, claim(s) 33-35, are drawn to a method for detecting an ischemic event by using antibodies.

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Group VI, claim(s) 36-42, 47-51 and 70-73, are drawn to diagnostic kits.

Group VII, claim(s) 43-46, are drawn to a method for detecting an ischemic event by determining the amount of nickel ion.

Group VIII, claim(s) 52-56, are drawn to a ligand.

Group IX, claim(s) 57-61, are drawn to a composition of Cu, Ni and Co.

Group X, claim(s) 62-64 and 78, are drawn to a method of calibrating analyzer.

Group XI, claim(s) 65-69, are drawn to a method of detecting albumin which lacks N-terminal amino acids of SEQ ID NO: 1

Group XII, claim(s) 74-77, are drawn to a calibrator composition.

4. The inventions listed as Groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The special technical feature linking group I-XII appears to be a method for detecting an ischemic event in a patient.

However, Bar-Or et al. (US patent 5,227,307 and 5,290,519) teach methods and kits for detecting an ischemic event in a patient (see abstract, title and claims in both patents).

Therefore, the technical feature linking the inventions of groups I- XII does not constitute a special technical feature as defined by the PCT Rule 13.2, as it does not define a contribution over the prior art. As set forth above, each of group I-XII has a special technical feature that is not required for the other groups.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the

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currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Election***

6. This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

a- If applicants elect group I, then there are additional election of species.

Please choose one of the species (metal ion salt) from claim 4.

Please choose one of the species (assays) from claim 6.

b- If applicants elect group II, then there are additional election of species.

Please choose one of the species (samples) from claims 11 or 12.

Please choose one of the species (metal ion salt) from claim 9.

c- If applicants elect group III, then there are additional election of species.

Please choose one of the species (assays) from claim 20.

d- If applicants elect group VI, then there are additional election of species.

Please choose one of the species (Kits) from claims 36, 47 or 70.

e- If applicants elect group VIII, then there are additional election of species.

Please choose one of the species (ligands) from claims 52, 53, 54, 55 or 56.

f- If applicants elect group IX, then there are additional election of species.

Please choose one of the species (derivatives) from claims 65, 66, 67, 68 or 69.

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The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:

The species are shown to be distinct because they are drawn to a plurality of disclosed patentably distinct methods and compounds comprising different method steps and structurally and functionally distinct molecules.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim(s) are generic: 1, 9, 19, 28, 33, 36, 41, 42, 43, 47, 52-57, 67, 68, 70, 71, 74 and 82.

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***Conclusion***

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Khatol S Shahnan-Shah whose telephone number is (703) 308-8896. The examiner can normally be reached on 7:30am-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette F Smith can be reached on (703) 308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Khatol Shahnan-Shah, BS, Pharm, MS

Biotechnology Patent Examiner

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September 30, 2002

  
LYNETTE R. F. SMITH  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600